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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,882	03/08/2004	David Radunsky	067062.0127	2882

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EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/796,882

Applicant(s)

RADUNSKY ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received:
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0807,1007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-28 and 30-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,787,040 in view of

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Kotitschke patent 4,900,720 and Hoffman et al patent 5,661,124. The instant claims parallel the language of the allowed '040 claims concerning limitations directed towards circulating of blood through a very large pore hemofilter, removing ultrafiltrate and replacing the ultrafiltrate with a replacement fluid having clean target receptor molecules. The instant claims lack the limitations of providing of sufficient clean albumin to maintain adequate osmotic pressure and providing of clean albumin and target receptor molecules to attract inflammatory mediators and toxins. However Kotitschke teach application of a replacement fluid having such target receptor molecules (column 1, lines 37-45 and column 3, lines 35-52) and Hoffman teaches sufficient albumin to maintain osmotic pressure (column 20, line 64-column 21, line 26), both teachings having motivations concerning the well-being and overall health of the replacement fluid.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al patent 6,287,516 in view of Ash patent 5,919,369. Matson et al disclose an extracorporeal circuit for treating blood comprising the patient and blood vessels, line 101/107 adapted to remove and return the patient's blood, large pore blood hemofilter 102 operable to form a stream of filtered blood that travels through line 105 and stream of ultrafiltrate that passes through line 115/131, the hemofilter having a nominal molecular weight cutoff of about 150,000 Daltons, and pumps 104 and 106a operable to vary ultrafiltration rates through the circuit. Disclosed blood flow rates of up to 9 liters/hour (column 14, lines 58-60) are achieved. Also disclosed is a source (column 8, lines 8-14 and column 9, lines 2-12 and 31-33) for infusing a replacement fluid into the patient and therefor the blood circuit. Compositions contained in such source are accorded little patentable weight since composition substance does not constitute any structural apparatus feature.

The claims all differ in requiring the hemofilter to have a cutoff of actually greater than 150,000 Daltons. Ash teaches such hemofilters at column 7, lines 4-8 and 14-16. It would have

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been obvious to one of ordinary skill in the art to have utilized a hemofilter of slightly higher molecular weight cutoff in the Matson circuit, as suggested by Ash, in order to remove middle molecular weight blood toxins.

Claims 18-23 merely recite additional characteristics of fluid materials utilized by the apparatus structure, and do not further define structural features or limitations.

Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash patent 5,919,369 in view of Davidner et al patent 6,193,681. Ash et al disclose an extracorporeal circuit for treating blood comprising the patient and blood vessels, line 121/122/131 adapted to remove and return the patient's blood, large pore or very large pore blood hemofilter 128 (column 7, lines 9-25) operable to form a stream of filtered blood that travels through line 129 and stream of recirculating fluid that passes through line 135/137, the hemofilter having a nominal molecular weight cutoff ranging from values below 150,000 Daltons up to 1,000,000 Daltons, and pumps 104 and 106a operable to vary ultrafiltration rates through the circuit. Also disclosed is a source (column 8, lines 8-14 and column 9, lines 2-12 and 31-33) for infusing a replacement fluid into the patient and therefor the blood circuit. Compositions contained in such source are accorded little patentable weight since composition substance does not constitute any structural apparatus feature.

The claims differ in requiring that the blood filter is operable to form streams of both filtered blood and ultrafiltrate from the patient's blood flowing therethrough and at ultrafiltration rates of between 2 and 20 liters per hour. However, Davidner teach hemofilter 106 (column 7, lines 8-30) so operable, forming filtered blood stream 107 and ultrafiltrate stream 108 (column 5, lines 17-43). Davidner teaches flow rates of 400-500 ml/min at column 5, lines 18-20 which

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equate to approximate flow rate of 2-20 liters per hour. It would have been obvious to one of ordinary skill in the art to have modified the Ash system by designing the hemofilter and circuit to form flow of ultrafiltrate and flow of filtered fluid in such manner to effect such ultrafiltration rates, to maintain system blood pressure, simplify the circuit, and prevent and treat septicemia conditions.

Claims 18-23 merely recite additional characteristics of fluid materials utilized by the apparatus structure, and do not further define structural features or limitations.

Claims 24-29 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash patent 5,919,369 in view of Davidner et al patent 6,193,681 and Kotitschke patent 4,900,720.

Ash et al disclose an extracorporeal circuit for treating blood comprising the patient and blood vessels, line 121/122/131 adapted to remove and return the patient's blood, large pore or very large pore blood hemofilter 128 (column 7, lines 9-25) operable to form a stream of filtered blood that travels through line 129 and stream of recirculating fluid that passes through line 135/137, the hemofilter having a nominal molecular weight cutoff ranging from values below 150,000 Daltons up to 1,000,000 Daltons, and pumps 104 and 106a operable to vary ultrafiltration rates through the circuit. Also disclosed is a source (column 8, lines 8-14 and column 9, lines 2-12 and 31-33) for infusing a replacement fluid into the patient and therefor the blood circuit. Compositions contained in such source are accorded little patentable weight since composition substance does not constitute any structural apparatus feature.

The claims differ in requiring that the blood filter is operable to form streams of both filtered blood and ultrafiltrate from the patient's blood flowing therethrough and at ultrafiltration

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rates of between 2 and 20 liters per hour. However, Davidner teach hemofilter 106 (column 7, lines 8-30) so operable, forming filtered blood stream 107 and ultrafiltrate stream 108 (column 5, lines 17-43). Davidner teaches flow rates of 400-500 ml/min at column 5, lines 18-20 which equate to approximate flow rate of 2-20 liters per hour. It would have been obvious to one of ordinary skill in the art to have modified the Ash system by designing the hemofilter and circuit to form flow of ultrafiltrate and flow of filtered fluid in such manner to effect such ultrafiltration rates, to maintain system blood pressure, simplify the circuit, and prevent and treat septicemia conditions.

The method claims also differ in requiring that the replacement infusion fluid contains clean target receptor molecules. However, Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the formulation being in solution) that is formulated to treat many toxic diseases (column 1 lines 37-45, etc.), and contains albumin (up to 35-50 g/l or more), inflammatory mediators (igG, igA) and other receptor molecules (column 3, lines 35-52). The albumin and other constituents in the replacement fluid medium are rendered sterilized or "clean", as claimed, by ultrafiltration, exposure to a propiolactone sterilizing substance and exposure to ultraviolet (UV) radiation (column 3, lines 45-51 and several sections of text of column 6, lines 32-66). The albumin and other constituents also have binding sites operable to attract inflammatory mediators from tissue of the patient. It would have been obvious to one of ordinary skill in the art to have included the clean target receptor molecules with the infusion fluid of Ash, as taught by Kotitschke, in order to treat diseases of the patient whose blood is being purified.

For claims 26-29, the infusion fluid may contain a concentration of albumin which may fall within a specific claimed concentration range of between about 0.5 g/100 ml (5g/l) to 20 g/ml (200g/l), (see Kotitschke at column 3, line 38, and Tables at columns 7 & 8). Kotitschke also teaches various specific receptor and inflammatory mediator molecules including igG, igA, igM, and macroglobulin.

For claims 31,32,34,35, and 42-44, Davidner teaches control of proportion of ultrafiltrate stream removed to drain or returned to the patient, cycling of ultrafiltrate pumping and routing and variation of rates of pumping of the ultrafiltrate stream (column 5, lines 32-42 and column 6, lines 25-28).

For claims 32 and 33, the ultrafiltrate stream may be cleaned by use of adsorbent material (Davidner column 5, lines 50-55 and Ash at column 14, lines 15-18).

For claims 36 and 37, fluid delivery may be concurrent with the hemofiltration (Ash at column 9, lines 48-50).

For claim 38 and 39, Kotitschke includes replacement receptor and inflammatory mediator molecules (see column 3, lines 29-47 concerning igG, igA, igM and macroglobulin) and discloses removal or treatment of inflammatory mediator toxins (Abstract).

For claims 40 and 41, Ash discloses infusing the replacement fluid directly into the patient or into the circuit (figure 2).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash patent 5,919,369 in view of Davidner et al patent 6,193,681 and Kotitschke patent 4,900,720, as applied to claims 24-28 and further in view of Hoffman et al patent 4,968,432. Claim 30 further differs by requiring the infusion fluid to contain sufficient albumin to maintain adequate oncotic

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pressure in the patient. Hoffman teaches sufficient albumin to maintain osmotic pressure, both teachings having motivations concerning the well-being and overall health of the replacement fluid.

Claims 24-29 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al patent 6,287,516 in view of Ash patent 5,919,369 and Kotitschke patent 4,900,720.

Matson et al disclose a method for removing toxic substances from the blood using an extracorporeal circuit for treating blood comprising the patient and blood vessels, line 101/107 adapted to withdraw and return the patient's blood, delivering it to a large pore blood hemofilter 102 operable to form a stream of filtered blood that travels through line 105 and stream of returned ultrafiltrate that passes through line 115/131, the hemofilter having a nominal molecular weight cutoff of about 150,000 Daltons, and pumps 104 and 106a operable to vary ultrafiltration rates through the circuit. Disclosed blood flow rates of up to 9 liters/hour (column 14, lines 58-60) are achieved. Also disclosed is a source (column 8, lines 8-14 and column 9, lines 2-12 and 31-33) for providing and infusing a clean ("physiological and isotonic") replacement fluid into the patient and therefor the blood circuit. Compositions contained in such source are accorded little patentable weight since composition substance does not constitute any structural apparatus feature.

The method claims all differ in requiring the hemofilter to have a cutoff of actually greater than 150,000 Daltons. Ash teaches such hemofilters at column 7, lines 4-8 and 14-16. It would have been obvious to one of ordinary skill in the art to have utilized a hemofilter of

slightly higher molecular weight cutoff in the Matson circuit, as suggested by Ash, in order to remove middle molecular weight blood toxins.

The method claims also differ in requiring that the replacement infusion fluid contains clean target receptor molecules. However, Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the formulation being in solution) that is formulated to treat many toxic diseases (column 1 lines 37-45, etc.), and contains albumin (up to 35-50 g/l or more), inflammatory mediators (igG, igA) and other receptor molecules (column 3, lines 35-52). The albumin and other constituents in the replacement fluid medium are rendered sterilized or “clean”, as claimed, by ultrafiltration, exposure to a propiolactone sterilizing substance and exposure to ultraviolet (UV) radiation (column 3, lines 45-51 and several sections of text of column 6, lines 32-66). The albumin and other constituents also have binding sites operable to attract inflammatory mediators from tissue of the patient. The disclosed solution also contains a balanced amount of salts and other electrolytes as with the infusion solution of Matson (column 6, lines 60-64 and Table concerning “Electrolytes” on column 7). It would have been obvious to one of ordinary skill in the art to have included the clean target receptor molecules with the infusion fluid of Matson, as taught by Kotitschke, in order to treat diseases of the patient whose blood is being purified.

For claims 26-29, the infusion fluid may contain a concentration of albumin which may fall within a specific claimed concentration range of between about 0.5 g/100 ml (5g/l) to 20 g/ml (200g/l), (see Kotitschke at column 3, line 38, and Tables at columns 7 & 8). Kotitschke

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also teaches various specific receptor and inflammatory mediator molecules including igG, igA, igM, and macroglobulin.

For claims 31,32,34,35, and 42-44, Matson discloses control of proportion of ultrafiltrate stream removed to drain or returned to the patient, cycling of ultrafiltrate pumping and routing and variation of rates of pumping of the ultrafiltrate stream (column 4, lines 9-13, column 12, lines 45-67 and column 14, lines 45-65).

For claims 32 and 33, the ultrafiltrate stream may be cleaned by use of adsorbent material (Matson column 14, lines 6-44).

For claims 36 and 37, fluid delivery may be concurrent with the hemofiltration (Matson at column 4, lines 9-13).

For claim 38 and 39, Kotitschke includes replacement receptor and inflammatory mediator molecules (see column 3, lines 29-47 concerning igG, igA, igM and macroglobulin) and discloses removal or treatment of inflammatory mediator toxins (Abstract).

For claims 40 and 41, Matson discloses infusing the replacement fluid directly into the patient or into the circuit (column 4, lines 10-13 and column 8, lines 8-15).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al patent 6,287,516 in view of Ash patent 5,919,369 and Kotitschke patent 4,900,720, as applied to claims 24-28 and further in view of Hoffman et al patent 4,968,432. Claim 30 further differs by requiring the infusion fluid to contain sufficient albumin to maintain adequate oncotic pressure in the patient. Hoffman teaches sufficient albumin to maintain osmotic pressure, both teachings having motivations concerning the well-being and overall health of the replacement fluid.

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Applicant's arguments with respect to claims 17-44 have been considered but are moot in view of the new grounds of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can be reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

November 09, 2007


JOSEPH DRODGE
PRIMARY EXAMINER